REMARKS

The following remarks and the above amendments are submitted to address all issues in this case, and to put this case in condition for allowance. Amendments are made solely to better define the subject matter of the present invention. These amendments are supported by the disclosure of the application as filed and are believed to provide no new subject matter. After the above amendments, application claims 10, and 12-20 are pending in the application. Application claims 1-9 and 11 are withdrawn. Application claims 10 and 16 are the only independent claims.

Applicants have studied the Office Action mailed April 28, 2009 and have the following remarks.

35 U.S.C. 112

New Matter

The Examiner has rejected claims 10 and 12-13 under 35 U.S.C. 112, first paragraph, asserting that these claims do not comply with the written description requirement. The Examiner asserts that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that the limited number of specific preferred embodiments disclosed at page 6 of the instant specification does not provide support for the transition phrase "consisting essentially of" or define the specific components as "essential."

The Applicant respectfully traverses this rejection. Respectfully, the Examiner is reminded that, to satisfy the written description requirement, the specification simply has to describe the invention with all of its claimed limitations. *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). One does that by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention. *Id.* Notably, the specification is only required to contain an equivalent description of the claimed subject matter, the exact terms need not be used *in haec verba*. *Id.*

The transitional phrase "consisting essentially of" limits the scope of the claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. *See* MPEP 2111.03. As correctly noted by the Examiner, there must be a clear indication in the specification or the claims of the basic and novel characteristics of the invention. *Id*; *See, e.g., AK Steel Corp. v. Sollac,* 344 F.3d 1234, 1240-41 (Fed. Cir. 2003)(Applicant's statement in the specification that "silicon contents in the coating should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.).

Taken together, to satisfy the written description requirement of § 112, the exact terms, "consisting essentially of" or "essential" need not be specifically used in the specification to satisfy the written description requirement for claims 10 and 12-13. Rather, the specification need only contain a discussion on the basic novel characteristics

of the invention. Applicant respectfully asserts that the instant specification accomplishes this, and provides written support for claims 10 and 12-13.

The specification identified the problems of the prior art as the general thought that when ingesting a low dose of GLU, GLU would largely be extracted by the splanchnic area for oxidation and transamination, resulting in only a very small increase in systemic plasma GLU. *See* p 9, lns 11-16. When this was the case, the GLU concentrate would not rise significantly in skeletal muscle. *Id.* Thus, there was a need to develop a GLU enriched drink that was able to increase plasma GLU concentration. *See* p 9, lns 17-18. Accordingly, pilot studies were performed to in order to obtain the optimal dose of glutamate to increase plasma GLU concentration. *See* pp 9-10, lns 29-13. Based on the results of the pilot studies, it was discovered that ingestion of GLU in a manner that would increase plasma GLU concentration may be a novel and an efficient substrate to restore the decreased muscle levels in COPD. *See* p 10, lns 15-16.

As a result of the pilot studies, among other research and studies, disclosed in the specification of the present application are compositions for the treatment or prophylaxis of COPD and other acute and chronic diseases wherein " *the active ingredients [are] glutamate and/or its precursor forms*," and the amount of the active ingredients to be administered is usually within the range of up to 3 grams per dose, with a daily dose range of about 9-20 grams for an adult. *See* pp 10 – 11, lns 27-30, 5-7, 15-23. There is a clear indication in the specification of the basic and novel characteristic of the invention, *i.e.*, the active ingredients of glutamate and/or its precursor forms, administered in an effective dose range dependant upon the characteristics of the individual being treated (*e.g.*, 9-20 grams daily for a 75 kg adult). Thus, the active, novel, and essential

components of the disclosed compositions (*i.e.*, the active ingredients of glutamate and/or its precursor forms) are clearly indicated in the specification of the present application in the combination of the discussion of the pilot studies and the identification of these components as the "active ingredients" of the disclosed compositions. For all the forgoing reasons, the Applicant respectfully requests that the Examiner withdraw his rejections to claims 10 and 12-13 under 35 U.S.C. 112, first paragraph, as Applicant has shown that these claims do comply with the written description requirement.

Second Paragraph

The Examiner has also rejected claim 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Examiner contends that the phrase "associated" is a relative term which renders the claim indefinite. Without admission as to the correctness of the Examiner's rejection, claim 13 has been amended to remove the phrase "associated," mooting the Examiner's rejection of claim 13 under U.S.C. 112, second paragraph.

35 U.S.C. 103

The Examiner rejects claims 10 and 12-13 under 35 U.S.C. 103(a) as being unpatentable over the combination of Pouw, *et al.* (American Journal of Respiratory Critical Care Medicine, vol 158, 1998, 797-801) in view of Meiji Milk Prod Ltd (EP 0873754). The Examiner is respectfully reminded that, even under the relaxed standards of *KSR*, the Examiner must show each element of the Applicant's claimed invention and sufficient reasoning for a combination in order to make a *prima facie* case for obviousness. Applicant respectfully traverses the Examiner's rejection as the above

references fail to show all the elements of the claims, as amended, and Applicant's new claims and there is no reasonable explanation for modifying the references to obtain the claims as amended.

The Examiner states that Pouw, *et al.* reports the finding that in patients with COPD, the glutamic acid level in muscles and plasma is decreased, but does not teach treatment of the same. The Examiner attempts to fill in the holes of Pouw, *et al.* with Meiji Milk Prod. Co. Ltd., stating that Meiji teaches a a composition for increasing the amino acid level in a patient's blood supply, which includes glutamic acid, leucine, valine and isoleucine (claim 9). Then, the Examiner states that where the amino acid content of the blood supply is increased, one of ordinary skill in the art would reasonable except the amino acid content of the muscles to increase, given the function of blood is to transport nutritional components to the body.

Applicant respectfully traverses this rejection. As noted by the Examiner, Pouw, *et al.* identifies that the glutamic acid level in the muscles of patients with COPD is decreased. However, as also noted by the Examiner, Pouw, *et al.* does not disclose any treatment for this condition. Meiji Milk Prod. Co. Ltd, the reference used by the Examiner to fill the holes of Pouw, *et al*, can not fill these holes.

As a preliminary matter, the Examiner is reminded that prior to the disclosure of the compositions of Applicant's application, the problem in the prior art was that when ingesting a low dose of glutamate, the glutamate would largely be extracted by the splanchnic area for oxidation and transamination, resulting in only a very small increase in systemic plasma. When this was the case, the GLU concentrate would not rise significantly in skeletal muscle.

The compositions of Meiji do not address and are unable to fill the holes of Pouw, *et al.*, and to solve this problems in the prior art, for several reasons. First, while the compositions of Meiji contain glutamic acid, it is specifically noted in the specification of Meiji that "since histidine and glutamic acid are relatively low in content and effect of lipid induction, it is possible to obtain the intended objects without the addition of these two amino acids." *See* p 7, lns 22-23. Thus, glutamic acid is not an essential or active component of the compositions of Meiji. In fact, the specification of Meiji explicitly teaches away from a composition wherein the only active ingredient is glutamic acid.

Second, when included in the composition of Meiji as a component, the glutamic acid is present in an extremely small molar ratio, *e.g.*, 2.8 to 8.8 moles. As described more fully in Applicant's specification, such a small molar ratio would not function as the Examiner asserts (increase the blood supply / increase the amino acid content of the muscles). Rather, this small amount of glutamic acid would largely be extracted by the splanchnic area, resulting in no significant increase glutamic acid in the skeletal muscles.

Third, the compositions of Meiji contain amino acids, such as proline and alanine, which are apparently essential and which are not present in Applicant's claims. As noted previously, the essential and active elements in Applicant's composition are glutamate and a precursor thereof from the group consisting of valine, isoleucine, and a keto acid thereof. Thus, the composition of Meiji contains essential elements that are not essential to Applicant's claimed method, and, conversely, Applicant's method contains essential elements which are not essential to Meiji. For at least these reasons, Applicant's claims are non-obvious in light of the combination of Pouw *et al.* and Meiji Milk Prod. Co. Ltd. The Examiner is respectfully requested to withdraw his rejection.

Applicant also notes that the Examiner did not address Applicant's pending claims 14 and 15 in the April 28, 2009 Office Action. Accordingly, the Applicant assumes that these claims are allowable over the Examiner's cited prior art references.

CONCLUSION

In light of the above, Applicant respectfully contends that the pending claims are patentable over the cited art and requests entrance of the above amendments and allowance of all pending claims so that this case can pass on to issue.

As a final point, there is also included herewith a petition for a one month extension of time and the associated petition fee. Also enclosed herein is a Request for Continued Examination and the associated fee. It is believed no other fees are due in conjunction with this filing; however, the Commissioner is authorized to credit any overpayment or charge and deficiencies necessary for entering this amendment, including any claims fees and/or extension fees to/from our **Deposit Account No. 50-0975**.

Respectfully submitted,
Lewis, Rice & Fingersh, L.C.

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